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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,800	03/30/2005	David C Racenet	2863(203-3511)	5353

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EXAMINER	
LOPEZ, MICHELLE	

ART UNIT	PAPER NUMBER
3721	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,800	RACENET, DAVID C	
	Examiner	Art Unit	
	Michelle Lopez	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed on February 21, 2008.

Terminal Disclaimer

2. The Terminal Disclaimer filed February 21, 2008 is acknowledged. Therefore, the double patenting rejection has been overcome.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "32" has been used to designate both closure member and dynamic closure member (see paragraph 36 of the specification). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set

forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because it is in claim format and it does not include which is new in the art to which the invention pertains. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 26-27, 42-43, 45, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin (US 6,835,199). McGuckin discloses the claimed tool assembly comprising an anvil (50) and a cartridge (40) assembly, the cartridge (40) being movable in relation to the anvil (50) between a spaced position and an approximated position, and defining a tissue gap between them in the approximated position. A clamp member (60) movable from a first to a second position configured to maintain the proximal end of the cartridge and the anvil in juxtaposed alignment,

i.e. placed close together, when the clamp member is in the second position. A dynamic clamping member (70) movably with relation to the cartridge and anvil, configured to define a maximum tissue gap between the cartridge and anvil during ejection of fasteners as shown in figs. 13-15. Drive members connected to clamp and dynamic members being formed from a flexible cable (64, 74). A knife blade (84a) formed on the dynamic clamping member. The first position of the dynamic clamping member is adjacent a proximal end of the tool assembly and the second position is adjacent to a distal end of the tool assembly as shown in figs. 13-15. The cartridge has a plurality of staples (120) and pushers (118) as shown in fig. 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 28-33, 40-41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin (US 6,835,199) in view of Bolanos (5,690,269). McGuckin discloses a drive member as coaxial drive cable (64, 74), but fails to disclose wherein the cable includes an outer sheath and a center rod. Bolanos teaches the concept of a drive member having a coaxial drive cable with an outer sheath (200) and a center rod (70) for the purpose of properly articulating an endoscopic portion. It would have been obvious to one having ordinary skill in the art to have substituted McGuckin's cable by the coaxial drive cable as taught by Bolanos to articulate the tool assembly.

Bolanos also teaches wherein the center rod (70) is movable and axially movable with respect to the outer sheath (claims 29-30).

With respect to claim 31, it is deemed that Bolanos' center rod (70) is rotatable in relation to the outer sheath as shown in Fig. 8.

With respect to claim 32, Bolanos also shows wherein the outer sheath (200) is operably connected to a clamp member as shown in Fig. 12.

With respect to claim 33, Bolanos also shows wherein the center rod (70) is operably connected to a dynamic clamping member 136.

With respect to claims 40-41, the modified invention of McGuckin does not specifically disclose the outer sheath is selected from the group consisting of steel mesh, plastic, nitinol, and Kevlar. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided an outer sheath as claimed, since it has been held to be within the general skill in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With respect to claim 44, Bolanos also shows a drive collar wherein the outer sheath (200) is fixedly attached to a drive collar as shown in Fig. 12 (claim 44).

7. Claims 48-50 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin (US 6,835,199) in view of Milliman (US 6,669,073). McGuckin discloses the claimed dynamic clamping member having a lower flange, but fails to disclose an upper flange and at least one of the flanges having a rounded cross-section along an axis transverse to a longitudinal

axis on the cartridge. Milliman shows a surgical stapling device having a cartridge and anvil assembly, and a dynamic clamping with a upper and lower flanges, wherein the lower flange haa a rounded cross-section along an axis transverse to a longitudinal axis on the cartridge for the purposes of smoothly translate said dynamic clamping member within the cartridge assembly. It would have been obvious to one having ordinary skill in the art to have provided the lower flange of McGuckin's dynamic clamping member with a rounded cross-section as taught by Milliman for a smooth translation of the dynamic member within the cartridge.

McGuckin also discloses a knife blade (84a) formed on the central body portion of the dynamic clamping member between the upper and lower flanges as shown in fig. 14. The cartridge assembly (50) comprises a plurality of staples (120) and pushers (118). The upper and lower flanges (82a, 82b) are vertically aligned.

8. Claims 26, 34-39, 42-43, and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne (US 5,485,952) in view of Milliman (US 6,669,073). Fontayne discloses a tool assembly comprising an anvil (18) and a cartridge assembly (16), the cartridge assembly having a plurality of fasteners and being movable in relation to the anvil between a spaced position and an approximated position. A clamp member (90) positioned adjacent a proximal end of the cartridge assembly and the anvil and being movable from a first position to a second position to maintain the proximal end of the cartridge assembly and the anvil in juxtaposed alignment, i.e. placed close together, (as shown in figs. 10-12) wherein a tissue gap (at the vicinity of 310) is formed between the anvil and cartridge assembly. A dynamic clamping member at the proximal end of (280) movable positioned in relation to the anvil and the cartridge assembly (as shown in figs. 4 and 12-14).

The language in claim 26, last paragraph, "configured to define a maximum tissue gap" is functional and afforded light weight because it is predicated on a future act. Furthermore, the functional language is no supported by sufficient structure capable of define said maximum tissue gap. Additionally, the specification has been carefully reviewed by the examiner, and it is the opinion of the examiner that the specification appears to suggest that the "maximum tissue gap" is defined by the space provided between upper and lower portions of the dynamic clamping member, wherein said portions need not be slidably positioned in recesses but rather need only engage an upper bearing surface on anvil and a lower bearing surface on cartridge assembly (as shown in paragraphs 13 and 36 of the instant invention specification). Therefore, it is deemed that the upper and lower portions of Fontayne's dynamic clamping member at vicinity of (265, 289) indeed engage an upper bearing surface of the anvil and a lower bearing surface of the cartridge (as shown in figs. 12-14), thereby defining the claimed maximum tissue gap therebetween.

Fontayne also discloses wherein the tool assembly is pivotally secured to a body portion (12) of a stapling device (claim 34). The tool assembly is operably connected to a collar member (154) and the collar member is pivotally secured to the body portion of the stapling device as shown in figs. 8-10 (claim 35). The tool assembly is rotatably mounted to the collar member as shown in Fig. 8 (claim 36). The dynamic clamping member is supported in the tool assembly as shown in figs. 12-14 (claim 37). The clamp member (90) is annular and is positioned about a proximal end of the anvil and of the cartridge assembly in its second position (claim 39). A knife blade (265) formed on the dynamic clamping member (claims 42-43). The first position of the dynamic clamping member is adjacent a proximal end of the tool assembly and the second

position of the dynamic clamping member is adjacent a distal end of the tool assembly (claim 45). A sled (276) and at least one pusher (304); the sled being driven by the dynamic clamping member as shown in Fig. 4 (claim 46, 51); and a plurality of staples (302) and pushers (304) (claim 47, 52); a knife blade (265) (claims 49-50).

With respect to claims 38 and 48, Milliman also shows a dynamic clamping member having upper and lower flange portions (12a-12b) engaging a surface of the anvil and cartridge, wherein such is deemed to define a maximum tissue gap therebetween. The lower flange portion of the dynamic clamping member has a rounded cross-section (287) as shown in Figs. 12A-12B. The flange portions are vertically aligned and a knife blade (280) disposed on a central body portion between the upper and the lower flange portions (claims 53-54).

9. Claims 27-33, 40-41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne 5,485,952 in view of Milliman 6,69,073, as applied to claims 26-27 as discussed above, and further in view of Bolanos (5,690,269).

The modified tool assembly of Fontayne fails to disclose wherein the drive member is flexible cable as a coaxial drive cable including an outer sheath and a center rod. Bolanos teaches the concept of a drive member having a coaxial drive cable with an outer sheath (200) and a center rod (70) for the purpose of properly articulating an endoscopic portion. It would have been obvious to one having ordinary skill in the art to have substituted Fontayne's drive member by a coaxial drive cable as taught by Bolanos to articulate the tool assembly.

Bolanos also teaches wherein the center rod (70) is movable and axially movable with respect to the outer sheath (claims 29-30). It is deemed that Bolanos' center rod (70) is rotatable

in relation to the outer sheath as shown in Fig. 8 (claim 31). Bolanos also shows wherein the outer sheath (200) is operably connected to a clamp member via (130a, 130b, 134) as shown in figs. 6-7 and wherein the center rod (70) is operably connected to a dynamic clamping member via (136) (claims 32-33).

With respect to claims 40-41, the modified invention of Fontayne does not specifically disclose wherein the center rod is formed from wound flexible cable and that the outer sheath is selected from the group consisting of steel mesh, plastic, nitinol, and Kevlar. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a wound flexible cable and an outer sheath as claimed, since it has been held to be within the general skill in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With respect to claim 44, Bolanos also shows a drive collar (185) wherein the outer sheath (200) is fixedly attached to the drive collar as shown in figs. 6-7 (claim 44).

Response to Arguments

10. Applicant's arguments filed February 21, 2008 have been fully considered but they are not persuasive. Applicant contend that neither Fontayne nor Milliman disclose a tool assembly which includes a dynamic clamping member configured to define a maximum tissue gap between the cartridge and anvil adjacent the dynamic clamping member during ejection of the staplers. This is not found persuasive as claims are given their broadest reasonable interpretation consistent with the specification. In this instance, claims 26 and 48 do not recite any structure capable of performing the function that applicant is referring to, i.e. configured to define a

maximum tissue gap. Also, the specification appears to suggest that the "maximum tissue gap" is defined by the space provided between upper and lower portions of the dynamic clamping member, wherein said portions need not be slidably positioned in recesses but rather need only engage an upper bearing surface on anvil and a lower bearing surface on cartridge assembly (as shown in paragraphs 13 and 36 of the instant invention specification). Therefore, it is the examiner's position that Fontayne's tool assembly, at one point of the operation wherein the dynamic clamping member is being translated forward within the anvil and cartridge assembly, define a maximum tissue gap at vicinity of (310) by engagement of portions (265, 289) with the anvil and cartridge.

Applicant also contends that Milliman can not be incorporated into Fontayne's device without destroying the functionality of Fontayne. In particular, applicant states that Milliman's drive assembly (212) is configured to move the anvil assembly (20) to a closed position as well as define a maximum tissue gap, and that Milliman's drive assembly would replaces Fonatyne's clamp member. However, it should be noted that Milliman is relied upon to show the use of a dynamic clamping member having upper and lower flanges portions. It is acknowledged that Fontayne's device operates differently from Milliman's device; however, both show the concept of defining a maximum tissue gap. It would be within the abilities of one having ordinary skill in the art to apply Milliman concept of having a dynamic clamping member with upper and lower flanges in order to slidably engage said flanges within recesses formed on both the anvil and cartridge assembly maintaining a uniform tissue gap during firing of the device.

For the reasons above, the grounds of rejection are deemed proper.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Lopez whose telephone number is 571-272-4464. The examiner can normally be reached on Monday - Thursday: 8:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ML/
Patent Examiner

/Rinaldi I Rada/
Supervisory Patent Examiner, Art Unit 3721